

**REMARKS****Claim Status**

Claims 1-12, 15-16, 19-32, 37, 44 and 45 are pending in this application and stand rejected. Upon entry of this response, claims 1-12, 15-16, 19-32, 37, 44 and 45 are currently pending and under consideration.

Applicants respectfully request reconsideration in view of the following remarks.

**Commonly Owned Invention**

Applicants respectfully point out that the application was commonly owned and an assignment was recorded: Notice of Recordation of Assignment Document with a Recordation Date: 07/29/2002 REEL/FAME: 013141/0650.

**Rejections under 35 U.S.C. § 103**

Claims 1-12, 15, 16, 19-32, 37, 44 and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 98/34644 in view of Chen (U.S. 6,602,274).

The Office contends that it would have been obvious to one of ordinary skill in the art to treat inflammation arising from photodynamic therapy using low dose photodynamic therapy as an anti-inflammatory agent. The Office asserts that WO 98/34644 is said to teach the steps of 1) bringing the injured tissues or “pre-injured tissues” with a photosensitizing agent capable of penetrating into the tissue 2) exposing the tissue to the light having wave length absorbed by photosensitizing agent for a time sufficient to reduce or prevent the inflammation. The Office cites Chen as teaching that photodynamic therapy can cause damage to normal tissues surrounding or adjacent to the target tissue. The Office concludes that it would have been obvious to one skilled in the art to employ the teachings of the references to treat inflammation arising from photodynamic

therapy or any other source using low dose photodynamic therapy as an anti-inflammatory agent to injured or pre-injured tissue.

Applicants respectfully traverse the rejection.

The instant claims are directed to a method for reducing or preventing inflammation of an tissue arising from normal dose photodynamic therapy by further subjecting the treated tissue to exposure with low-dose light. The Office has kindly acknowledged that WO 98/34644 differs from the instant claimed invention in reducing inflammation in tissues exposed to photodynamic therapy and tissues that overlap with the tissues that have been treated with normal dose photodynamic therapy.

Applicants reassert, as in their August 16, 2010 response, that WO 98/34644 describes appropriate irradiation conditions for low dose PDT as: irradiation at a dose of less than 15 J/cm<sup>2</sup> applied between 0-3 hours after administration of the photosensitizer, when significant amounts of the photosensitizer would still be expected to be present (page 36, lines 24-25). Particularly preferred conditions for use during surgery are said to include exposing the treated tissue to about 7-12 J/cm<sup>2</sup> of light (page 37, line 20). Table 1A and 1B on page 39 of WO 98/34644 shows that irradiation above 12 J/cm<sup>2</sup> resulted in vascularity, and poor bleb survival, indicators of inflammation (see, e.g., Table 1A and B, rabbit nos. 5 and 6, treated with 18 and 24 J/cm<sup>2</sup>, respectively). Applicants respectfully submit that these statements and data would have suggested to one of ordinary skill that there is a maximum PDT dose that will provide the anti-inflammatory effect and that at higher irradiation doses, inflammation occurs. One of ordinary skill in the art would not have believed that irradiation at a total light dose greater than the low dose photodynamic therapy reported by WO 98/34644 would have provided the anti-inflammatory effects.

The Office further asserts that irradiation at light doses of up to 100J/cm<sup>2</sup> is described by the prior art which allegedly reads on the irradiation claimed in claims 44 and 45. Applicants respectfully traverse this argument. Applicants respectfully note that in WO 98/34644, the irradiation of 100 J/cm<sup>2</sup> is under the condition that irradiation is applied later than six hours after

administration of photosensitizing agent (page 36, lines 26-27). Under these conditions, very little of the photosensitizing agent would still be present in the tissues, as described in WO 98/34644 (page 36, lines 10-15). In the instant claims, the photosensitizing agent is subjected to normal dose photodynamic treatment and immediately the tissue is further exposed to low dose treatment. Thus, the cited prior art does not teach the instant claims 44 and 45.

On page 3 of the Office Action dated December 9, 2010, the Office also asserts that Chen et al. teaches that normal tissue in the path of the beam will likely be activated and causes collateral normal skin damage. In other words, the normal tissue that is damaged in Chen et al. is tissue in the **path of the beam**, i.e. tissue that has been irradiated using normal dose PDT. Applicants submit that tissue in the path of the beam constitutes **treated tissue**. Hence, Chen cannot be taken to suggest that normal dose PDT results in inflammation in adjacent tissue regions that are **not** exposed to photoactivating light and so **not** exposed to normal dose PDT. Accordingly, Chen is clearly distinguishable from the invention as claimed, which relates to low dose PDT treatment of tissue areas which were previously **untreated** with photoactivating light (such as in normal dose PDT).

One skilled in the art could not piece together the teachings of the cited references to arrive at the present claims as the Office has suggested. In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 273012011800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 9, 2011

Respectfully submitted,

By:

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/Kausar Akhoon/

Kausar Akhoon

Registration No.: 66,803

MORRISON & FOERSTER LLP

12531 High Bluff Drive, Suite 100

San Diego, California 92130-2040

(858) 314-5133